



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/591,921

05/30/2007

Karl-Heinz Altmann

33683-US-PCT

5380

75074

7590

02/23/2010

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
220 MASSACHUSETTS AVENUE
CAMBRIDGE, MA 02139

EXAMINER

SHAMEEM, GOLAM M

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

02/23/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,921	Applicant(s) ALTMANN, KARL-HEINZ	
	Examiner Golam M. M. Shameem	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>07/21/09; 04/09/09; 09/07/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

This application is a 371 of PCT/EP05/02756 03/15/2005 and the claim of foreign priority under 35 U.S.C. § 119(a)-(d) to UK 0405898.8 03/16/2004 is acknowledged.

Status of Claims

Claims 1, 2, 4 and 5 are currently pending in the application. Claims 3 and 6-9 have been canceled.

Receipt is acknowledged of amendment / response filed on November 19, 2009 and that has been entered.

Information Disclosure Statement

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 07/21/2009, which has been entered in the file.

Response to Election/Restriction

In response to the restriction requirements, Applicants have elected Group I, which includes claims 1-5 drawn to a compound of formula I, and the elected species as set forth and disclosed in Example 2 (Response, page 5), **without** traverse is acknowledged. Applicant has canceled all non-elected subject matter and therefore, the restriction requirement is hereby withdrawn.

Applicants preserve their right to file a divisional on the non-elected subject matter.

Double Patenting

Art Unit: 1626

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 4, and 5 are rejected under the judicially created doctrine of obviousness-type double patenting, as being unpatentable over claims 11-18 and 21 of US 7,358,266 (US '266) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to the same art recognized subject matter. A reference anticipating one set of claim will render the other obvious and it would have been obvious to one of ordinary skill in the art at the time of the invention was made since US '266 patent teaches the generic compounds and compositions which are similar to the instantly claimed compounds.

The subject matter claimed in the instant application is fully disclosed and covered in US '266 patent. Therefore, the disclosures of US '266 patent that teaches many permutation and combinations (including various Markush variable substitutions, such as X and Ar etc), which would easily place Applicant's invention in possession of the public at the time of Applicant's invention was filed. The indiscriminate selection of "some" among "many" is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). Therefore, in the instant case, one skilled in the

Art Unit: 1626

chemical art would be motivated to choose to replace variable substitutions in permutation and combinations in core structure to obtain the desired products in view of the known teaching of the art. The claimed compounds are so closely related structurally to the homologous and /or analogous compounds of the reference as to be structurally obvious, therefore in the absence of any unobviousness or unexpected properties. Moreover, any other differences are but obvious structural modifications, which would be apparent to one skilled in the chemical art that can use similar substitutions, would expect to have the same or essentially the same results. Therefore, in looking at the instantly claimed invention as a whole, the claimed compounds and compositions would have been suggested to one skilled in the art and therefore, is obvious, absent evidence to the contrary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 4 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hoefle *et al* (US 6,288,237). Applicant claims Epothilone compounds, compositions and their process for preparation thereof. Hoefle *et al* also discloses several Epothilone derivatives and at least one of them anticipates the instantly claimed invention, wherein, R is H or alkyl, Y and Z together form the O atom of an epoxy group, C2 and C3 (in between) form a double bond and R¹ is H [US '237, claim 3, column 15], which reads on the instantly claimed compound.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Tuesday-Friday from 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone number for this Group is (571) 273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Art Unit: 1626

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

/Golam M. M. Shameem/

Primary Examiner

Art Unit 1626

Technology Center 1600

Application/Control Number: 10/591,921
Art Unit: 1626

Page 7

Application/Control Number: 10/591,921
Art Unit: 1626

Page 8